Claims:

1. A bioadhesive composition that comprises:

1) a particulate polymeric resin with an average particle size of less than or equal to about 100 μm and comprising at least about 55% by weight of carboxylic acid moieties based on the total weight of the polymeric resin;

2) from about 20 parts to about 250 parts by weight of a hydrophobic elastomeric component, based on 100 parts by weight of the resin; and

3) an amount of a drug effective to provide a desired therapeutic result,

wherein the resin and the drug are dispersed substantially throughout the elastomeric component, and which composition contains less than about 10% water by weight based on the weight of the polymeric resin, exhibits substantially no instantaneous adhesion to dry skin, and adheres to a mucosal surface.

2. A composition according to Claim 1, wherein the hydrophobic elastomeric component comprises a block styrene-butadiene-styrene copolymer, a block styrene-isoprene-styrene copolymer, a polyisobutylene, a polybutadiene, an isoprene rubber, a carboxy-functional polyisoprene, a hydroxy-functional polyisoprene, an acrylate elastomer, or a mixture of two or more of the foregoing.

3. A composition according to Claim 1, wherein the elastomeric component comprises a plasticizer.

4. A composition according to Claim 1, wherein the polymeric resin consists essentially of acrylic acid monomer units.

5. A composition according to Claim 4, wherein the resin is covalently crosslinked with about 0.75% to about 2% by weight based on the total weight of the resin of a polyalkenyl polyether.

6. A composition according to Claim 1, wherein up to about 30% of the carboxylic acid moieties of the resin are neutralized by a base.

7. A composition according to Claim 6, wherein the base is selected from the group consisting of $Al(OH)_3$ and $Ca(OH)_2$.

8. A composition according to Claim 6, wherein the base is a polyamine.

9. A composition according to Claim 1, wherein the elastomeric component is a hydrocarbon.

10. A composition according to Claim 9, wherein the elastomeric component comprises a polyisoprene with a molecular weight of about 500,000 to about 1,200,000 a polybutadiene with a molecular weight of about 100,000 to about 500,000, or a mixture thereof.

11. A composition according to Claim 9, wherein the elastomeric component is a mixture comprising about 5% to about 50% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 50% to about 95% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

12. A composition according to Claim 9, wherein the elastomeric component is a mixture comprising about 15% to about 25% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 75% to about 85% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

13. A composition according to Claim 9, wherein the elastomeric component is a mixture comprising about 20% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 80% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

14. A composition according to Claim 9, wherein the elastomeric component is a mixture comprising about 20% by weight of a polyisobutylene with a viscosity average molecular weight about 1.25 million and about 80% by weight of a polyisobutylene with a viscosity average molecular weight about 53,000.

15. A composition according to Claim 1, prepared by a process comprising the steps of:

1) adding to a mill the constituent or constituents of the elastomeric component;

2) milling the constituent or constituents of the elastomeric component to afford a substantially homogeneous elastomeric component;

3) milling the particulate polymeric resin, the drug, and the substantially homogeneous elastomeric component from step (2) to form a homogeneous composition.

16. A composition according to Claim 15, wherein the constituents of the elastomeric component comprise: about 5% to about 50% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million; and about 50% to about 95% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

17. A composition according to Claim 15, wherein the constituents of the elastomeric component comprise: about 15% to about 25% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 75% to about 85% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

18. A composition according to Claim 15, wherein the constituents of the elastomeric component comprise: about 20% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000

and about 2.5 million, and about 80% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

19. A composition according to Claim 15, wherein the constituents of the elastomeric component comprise: about 20% by weight of a polyisobutylene with a viscosity average molecular weight about 1.25 million and about 80% by weight of a polyisobutylene with a viscosity average molecular weight about 53,000.

20. A composition according to Claim 15, wherein the constituents of the elastomeric component comprise: about 60% to 100% of a polyisobutylene with a viscosity average molecular weight of about 750,000 to about 1,500,000; and 0% to about 40% of a polyisobutylene with a viscosity average molecular weight of about 40,000 to about 100,000.

21. A composition according to Claim 15, wherein the constituents of the elastomeric component are selected from the group consisting of a polyisoprene with a molecular weight of about 500,000 to about 1,200,000, a polybutadiene with a molecular weight of about 100,000 to about 500,000, a mixture of two or more of said polyisoprenes, a mixture of two or more of said polybutadienes, and a mixture of one or more of said polyisoprenes and one or more of said polybutadienes.

22. A composition according to Claim 1, wherein the resin has an average particle size between about 1 μm and about 80 μm.

23. A composition according to Claim 1, wherein the resin has an average particle size of between about 2 μm and about 10 μm.

24. A composition according to Claim 1, comprising about 20 to about 150 parts by weight of the elastomeric component based on 100 parts by weight of the resin.

25. A composition according to Claim 1, comprising about 25 to about 75 parts by weight of the elastomeric component based on 100 parts by weight of the resin.

26. A composition according to Claim 1, which contains less than about 4% water by weight based on the total weight of the resin.

27. A composition according to Claim 1, which contains less than about 2% water by weight based on the total weight of the resin.

28. A composition according to Claim 1, wherein the drug is one that exhibits systemic action.

29. A composition according to Claim 1, wherein the drug is a narcotic analgesic.

30. A composition according to Claim 1, wherein the drug is morphine or a pharmaceutically acceptable salt thereof.

31. A composition according to Claim 1, wherein the drug is selected from the group consisting of digoxin, heparin, hydromorphone, buprenorphine, theophylline, melatonin, and pharmaceutically acceptable salts thereof.

32. A composition according to Claim 1, wherein the resin is distributed substantially uniformly throughout the elastomeric component.

33. A composition according to Claim 1, wherein the resin is distributed throughout the elastomeric component in a suitable gradient.

34. A composition according to Claim 1, wherein the drug is distributed substantially uniformly throughout the elastomeric component.

35. A composition according to Claim 1, wherein the drug is distributed throughout the elastomeric component in a suitable gradient.

36. A composition according to Claim 1, wherein the drug is absorbed into the resin, adsorbed on the resin, or ionically bound to the resin.

37. A process for preparing a composition according to Claim 1 in a mill which process comprises the steps of:

1) milling the elastomeric component to afford a substantially homogeneous elastomeric component;

2) milling the particulate polymeric resin, the drug, and the substantially homogeneous elastomeric component from step (1) to form a substantially homogeneous composition.

38. A process according to Claim 37 wherein the drug is absorbed into the resin, adsorbed on the resin, or ionically bound to the resin prior to step (2).

39. A process for preparing a composition according to Claim 1, comprising the steps of:

(1) dissolving the elastomeric component in a volatile organic solvent;

(2) dispersing the resin and the drug substantially uniformly in the solution formed in step (1); and

(3) removing the solvent from the dispersion of step (2).

40. A process according to Claim 39, wherein the drug is absorbed into the resin, adsorbed on the resin, or ionically bound to the resin prior to step (2).

41. A sheet material comprising a composition according to Claim 1 with a flexible film backing applied thereto.

42. A bioadhesive composition that comprises:

1) a particulate polymeric resin with an average particle size of less than or equal to about 100 μm and comprising at least about 55% by weight of carboxylic acid moieties based on the total weight of the polymeric resin;

2) from about 20 parts to about 250 parts by weight of a hydrophobic elastomeric component, based on 100 parts by weight of the resin; and

3) an amount of a drug effective to provide a desired therapeutic result,

wherein the resin and the drug are dispersed substantially throughout the elastomeric component, and which composition contains less than about 10% water by weight based on the weight of the polymeric resin, exhibits substantially no instantaneous adhesion to dry skin, adheres to a mucosal surface, and exhibits a duration of adhesion to human oral mucosa of at least about 6 hours when tested according to the Test Method.

43. A composition according to Claim 42, which exhibits a duration of adhesion of at least about 8 hours when tested according to the Test Method.

44. A composition according to Claim 42, which exhibits a duration of adhesion of at least about 12 hours when tested according to the Test Method.

45. A composition according to Claim 42, wherein the hydrophobic elastomeric component comprises a block styrene-butadiene-styrene copolymer, a block styrene-isoprene-styrene copolymer, a polyisobutylene, a polybutadiene, an isoprene rubber, a carboxy-functional polyisoprene, a hydroxy-functional polyisoprene, an acrylate elastomer, or a mixture of two or more of the foregoing.

46. A composition according to Claim 42, wherein the elastomeric component comprises a plasticizer.

47. A composition according to Claim 42, wherein the polymeric resin consists essentially of acrylic acid monomer units.

48. A composition according to Claim 47, wherein the resin is covalently crosslinked with about 0.75% to about 2% by weight based on the total weight of the resin of a polyalkenyl polyether.

49. A composition according to Claim 42, wherein up to about 30% of the carboxylic acid moieties of the resin are neutralized by a base.

50. A composition according to Claim 49, wherein the base is selected from the group consisting of $Al(OH)_3$ and $Ca(OH)_2$.

51. A composition according to Claim 49, wherein the base is a polyamine.

52. A composition according to Claim 42, wherein the elastomeric component is a hydrocarbon.

53. A composition according to Claim 52, wherein the elastomeric component comprises a polyisoprene with a molecular weight of about 500,000 to about 1,200,000, a polybutadiene with a molecular weight of about 100,000 to about 500,000, or a mixture thereof.

54. A composition according to Claim 52, wherein the elastomeric component is a mixture comprising about 5% to about 50% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 50% to about 95% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

55. A composition according to Claim 52, wherein the elastomeric component is a mixture comprising about 15% to about 25% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 75% to about 85% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

56. A composition according to Claim 52, wherein the elastomeric component is a mixture comprising about 20% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 80% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

57. A composition according to Claim 52, wherein the elastomeric component is a mixture comprising about 20% by weight of a polyisobutylene with a viscosity average molecular weight about 1.25 million and about 80% by weight of a polyisobutylene with a viscosity average molecular weight about 53,000.

58. A composition according to Claim 1, prepared by a process comprising the steps of:

1) adding to a mill the constituent or constituents of the elastomeric component;

2) milling the contituent or constituents of the elastomeric component to afford a substantially homogeneous elastomeric component;

3) milling the particulate polymeric resin, the drug, and the substantially homogeneous elastomeric component from step (2) to form a substantially homogeneous composition.

59. A composition according to Claim 58, wherein the constituents of the elastomeric component comprise: about 5% to about 50% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million; and about 50% to about 95% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

60. A composition according to Claim 58, wherein the constituents of the elastomeric component comprise: about 15% to about 25% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 75% to about 85% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

61. A composition according to Claim 58, wherein the constituents of the elastomeric component comprise: about 20% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 80% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

62. A composition according to Claim 58, wherein the constituents of the elastomeric component comprise: about 20% by weight of a polyisobutylene with a

viscosity average molecular weight about 1.25 million and about 80% by weight of a polyisobutylene with a viscosity average molecular weight about 53,000.

63. A composition according to Claim 58, wherein the constituents of the elastomeric component comprise: about 60% to 100% of a polyisobutylene with a viscosity average molecular weight of about 750,000 to about 1,500,000; and 0% to about 40% of a polyisobutylene with a viscosity average molecular weight of about 40,000 to about 100,000.

64. A composition according to Claim 58, wherein the constituents of the elastomeric component are selected from the group consisting of a polyisoprene with a molecular weight of about 500,000 to about 1,200,000, a polybutadiene with a molecular weight of about 100,000 to about 500,000, a mixture of two or more of said polyisoprenes, a mixture of two or more of said polybutadienes, and a mixture of one or more of said polyisoprenes and one or more of said polybutadienes.

65. A composition according to Claim 42, wherein the resin has an average particle size of between about 1 μm and about 80 μm.

66. A composition according to Claim 42, wherein the resin has an average particle size of between about 2 μm and about 10 μm.

67. A composition according to Claim 42, comprising about 20 to about 150 parts by weight of the elastomeric component based on 100 parts by weight of the resin.

68. A composition according to Claim 42, comprising about 25 to about 75 parts by weight of the elastomeric component based on 100 parts by weight of the resin.

69. A composition according to Claim 42, which contains less than about 4% water by weight based on the total weight of the resin.

70. A composition according to Claim 42, which contains less than about 2% water by weight based on the total weight of the resin.

71. A composition according to Claim 42, wherein the drug is one that exhibits systemic action.

72. A composition according to Claim 42, wherein the drug is a narcotic analgesic.

73. A composition according to Claim 42, wherein the drug is morphine or a pharmaceutically acceptable salt thereof.

74. A composition according to Claim 42, wherein the drug is selected from the group consisting of digoxin, heparin, hydromorphone, buprenorphine, theophylline, melatonin, and pharmaceutically acceptable salts thereof.

75. A sheet material comprising a composition according to Claim 42 with a flexible film backing applied thereto.

76. A composition according to Claim 42, wherein the resin is distributed substantially uniformly throughout the elastomeric component.

77. A composition according to Claim 42, wherein the resin is distributed throughout the elastomeric component in a suitable gradient.

78. A composition according to Claim 42, wherein the drug is distributed substantially uniformly throughout the elastomeric component.

79. A composition according to Claim 42, wherein the drug is distributed throughout the elastomeric component in a suitable gradient.

80. A composition according to Claim 42, wherein the drug is absorbed into the resin, adsorbed on the resin, or ionically bound to the resin.

81. A process for preparing a composition according to Claim 42 in a mill which process comprises the steps of:

1) milling the elastomeric component to afford a substantially homogeneous elastomeric component;

2) milling the particulate polymeric resin, the drug, and the substantially homogeneous elastomeric component from step (1) to form a substantially homogeneous composition.

82. A process according to Claim 81 wherein the drug is absorbed into the resin, adsorbed on the resin, or ionically bound to the resin prior to step (2).

83. A process for preparing a composition according to Claim 42, comprising the steps of:

1) dissolving the elastomeric component in a volatile organic solvent;

2) dispersing the resin and the drug substantially uniformly in the solution formed in step (1); and

3) removing the solvent from the dispersion of step (2).

84. A process according to Claim 83, wherein the drug is absorbed into the resin, adsorbed on the resin, or ionically bound to the resin prior to step (2).

85. A patch comprising

1) a flexible film backing; and

2) a bioadhesive composition on one surface of the flexible film, the bioadhesive composition comprising

i) a particulate polymeric resin with an average particle size of less than or equal to about 100 μm and comprising at least about 55% by weight of carboxylic acid moieties based on the total weight of the polymeric resin;

ii) from about 20 parts to about 250 parts by weight of a hydrophobic elastomeric component, based on 100 parts by weight of the resin; and

iii) an amount of a drug effective to provide a desired therapeutic effect,

wherein the resin and the drug are dispersed substantially

throughout the elastomeric component, and which composition contains less than about 10% water by weight based on the weight of the polymeric resin, exhibits substantially no instantaneous adhesion to dry skin, and adheres to a mucosal surface,

which patch is further characterized in that it exhibits a duration of adhesion to human oral mucosa of at least about 6 hours when tested according to step 2 of the Test Method.

86. A patch according to Claim 85, wherein the hydrophobic elastomeric component comprises a block styrene-butadiene-styrene copolymer, a block styrene-isoprene-styrene copolymer, a polybutadiene, a polyisobutylene, an isoprene rubber, a carboxy-functional polyisoprene, a hydroxy-functional polyisoprene, an acrylate elastomer, or a mixture of two or more of the foregoing.

87. A patch according to Claim 85, wherein the elastomeric component comprises a placticizer.

88. A patch according to Claim 85, wherein the polymeric resin consists essentially of acrylic acid monomeric units.

89. A patch according to Claim 85, wherein the resin is covalently crosslinked with about 0.75% to about 2% by weight of a polyalkenyl polyether.

90. A patch according to Claim 85, wherein up to about 30% of the carboxylic acid moieties of the resin are neutralized by a base.

91. A patch according to Claim 90, wherein the base is selected from the group consisting of $Al(OH)_3$ and $Ca(OH)_2$.

92. A patch according to Claim 90, wherein the base is a polyamine.

93. A patch according to Claim 85, wherein the elastomeric component is a hydrocarbon.

94. A patch according to Claim 93, wherein the elastomeric component comprises a polyisoprene with a molecular weight of about 500,000 to about 1,200,000, a

polybutadiene with a molecular weight of about 100,000 to about 500,000, or a mixture thereof.

95. A patch according to Claim 93, wherein the elastomeric component is a mixture comprising about 5% to about 50% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 50% to about 95% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

96. A patch according to Claim 93, wherein the elastomeric component is a mixture comprising about 15% to about 25% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 75% to about 85% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

97. A patch according to Claim 93, wherein the elastomeric component is a mixture comprising about 20% of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 80% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

98. A patch according to Claim 93, wherein the elastomeric component is a mixture comprising about 20% by weight of a polyisobutylene with a viscosity average molecular weight about 1.25 million and about 80% by weight of a polyisobutylene with a viscosity average molecular weight about 53,000.

99. A patch according to Claim 85, prepared by a process comprising the steps of:

1) adding to a mill the constituent or constituents of the elastomeric component;

2) milling the constituent or constituents of the elastomeric component to afford a substantially homogeneous elastomeric component;

3) milling the particulate polymeric resin, the drug, and the substantially homogeneous elastomeric component from step (2) to form a substantially homogeneous composition; and

4) applying the flexible film backing to the composition from step (3).

100. A patch according to Claim 99, wherein the constituents of the elastomeric component comprise: about 5% to about 50% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million; and about 50% to about 95% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

101. A patch according to Claim 99, wherein the constituents of the elastomeric component comprise: about 15% to about 25% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 75% to about 85% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

102. A patch according to Claim 99, wherein the constituents of the elastomeric component comprise: about 20% by weight of a polyisobutylene with a viscosity average molecular weight between about 500,000 and about 2.5 million, and about 80% by weight of a polyisobutylene with a viscosity average molecular weight between about 40,000 and about 100,000.

103. A patch according to Claim 99, wherein the constituents of the elastomeric component comprise: about 20% by weight of a polyisobutylene with a viscosity average molecular weight about 1.25 million and about 80% by weight of a polyisobutylene with a viscosity average molecular weight about 53,000.

104. A patch according to Claim 99, wherein the constituents of the elastomeric component comprise: about 60% to 100% of a polyisobutylene with a viscosity average molecular weight of about 750,000 to about 1,500,000; and 0% to about 40% of a polyisobutylene with a viscosity average molecular weight of about 40,000 to about 100,000.

105. A patch according to Claim 99, wherein the constituents of the elastomeric component are selected from the group consisting of a polyisoprene with a molecular weight of about 500,000 to about 1,200,000, a polybutadiene with a molecular weight of about 100,000 to about 500,000, a mixture of two or more of said polyisoprenes, a mixture of two or more of said polybutadienes, and a mixture of one or more of said polyisoprenes and one or more of said polybutadienes.

106. A patch according to Claim 85, wherein the resin has an average particle size of between about 1 μm and about 80 μm.

107. A patch according to Claim 85, wherein the resin has an average particle size of between about 2 μm and about 10 μm.

108. A patch according to Claim 85, comprising about 20 to about 150 parts by weight of the elastomeric component based on 100 parts by weight of the resin.

109. A patch according to Claim 85, comprising about 25 to about 75 parts by weight of the elastomeric component based on 100 parts by weight of the resin.

110. A patch according to Claim 85, which contains less than about 4% water by weight based on the total weight of the resin.

111. A patch according to Claim 85, which contains less than about 2% water by weight based on the total weight of the resin.

112. A patch according to Claim 85, wherein the drug is one that exhibits systemic action.

113. A patch according to Claim 85, wherein the drug is a narcotic analgesic.

114. A patch according to Claim 85, wherein the drug is morphine or a pharmaceutically acceptable salt thereof.

115. A patch according to Claim 85, wherein the drug is selected from the group consisting of digoxin, heparin, hydromorphone, buprenorphine, theophylline, melatonin, and pharmaceutically acceptable salts thereof.

116. A patch according to Claim 85, wherein the resin is distributed substantially uniformly throughout the elastomeric component.

117. A patch according to Claim 85, wherein the resin is distributed throughout the elastomeric component in a suitable gradient.

118. A patch according to Claim 85, wherein the drug is distributed substantially uniformly throughout the elastomeric component.

119. A patch according to Claim 85, wherein the drug is distributed throughout the elastomeric component in a suitable gradient.

120. A patch according to Claim 85, which exhibits a duration of adhesion of at least about 8 hours when tested according to Step 2 of the Test Method.

121. A patch according to Claim 85, which exhibits a duration of adhesion of at least about 12 hours when tested according to Step 2 of the Test Method.

122. A method of achieving and/or maintaining a therapeutically effective blood level of a drug in a mammal, which method comprises the steps of:

a) adhering a composition according to Claim 1 to a mucosal surface of a mammal; and

b) allowing the composition to remain adhered for a time sufficient to release drug such that a therapeutically effective blood level of drug is achieved and/or maintained.

123. A method of achieving and/or maintaining a therapeutically effective blood level of a drug in a mammal, which method comprises the steps of:

a) adhering a patch according to Claim 85 to a mucosal surface of a mammal; and

b) allowing the patch to remain adhered for a time sufficient to release drug such that a therapeutically effective blood level of drug is achieved and/or maintained.

124. A method of delivering a drug to a mucosal surface of a mammal or to the vicinity of a mucosal surface of a mammal to provide a therapeutic effect on or in the vicinity of the mucosal surface, which method comprises the steps of:

a) adhering a composition according to Claim 1 to the mucosal surface;

b) allowing the composition to remain adhered for a time sufficient to release the drug to the mucosal surface or to the vicinity of the mucosal surface to provide the desired therapeutic effect.